

method of detecting involving nucleic acids. The Examiner concludes that restriction for examination purposes is proper because these inventions are allegedly independent and distinct for reasons given on pages 3 and 4 of the Office action.

Applicants respectfully request reconsideration and withdrawal of the restriction requirement because the restriction is unwarranted under the circumstances. There is good reason to keep all of the claims in this single application. Equitable considerations also justify a withdrawal, or at least a significant modification, of the restriction requirement.

Despite the statutory classes, there is unity of invention that can be seen through the basis of the whole invention, namely, the novel avian hepatitis E virus ("HEV"). This new avian HEV, which has been implicated in avian hepatitis-splenomegaly syndrome, gives rise to the remainder of the claimed subject matter including, but not limited to, its genetic makeup and the immunogenic uses thereof.

Many of the searches overlap and duplicate efforts. For example, searching Class 536, subclass 23.72, for each one of Groups II-VI will, in effect, require the same search in determining the novelty and nonobviousness of the avian HEV of Group I. The nucleotide sequences of ORF1 (SEQ ID NO:3), the RdRp gene (SEQ ID NO:5), the ORF2 gene (SEQ ID NO:7) and the ORF3 gene (SEQ ID NO:9) are found in the entire viral genome of SEQ ID NO:1. The novelty of the full-length sequence, in other words, sets the stage for the allowability of each of the partial nucleotide fragments of the whole sequence.

Similarly, Groups VII-X and XII overlap, require the same repetitive search of Class 424, subclass 225.1 (and others), and comprise a small, reasonable number of protein species that can be kept together in a single application. Insofar as the genetic composition of the new avian HEV is concerned, the nucleotides are closely interrelated with the proteins that they encode. Maintaining the proteins in the same application as the genes is permissible and often done by the U.S. Patent and Trademark Office. There is no statutory prohibition against claims drawn to proteins and nucleotides residing in the same issued patent.

Regarding the remaining groups, Group I is related to Group XIV in that the avian HEV sequence is directly connected to the method of detecting its presence in Claims 19 and 20. Group I is also related to Group XI as antigen-antibody formation and the use of the antibody in the immunoassay of Claims 17 and 18. Lastly, Group I is related to Group XIII because a search

for the avian HEV in the literature will, more likely than not, overlap with a search pertinent to attenuating pathogenic hepatitis E viruses.

In terms of equitable considerations, the restriction requirement effectively denies Applicants their substantive right to decide what they regard as their invention. By the Office's piecemeal approach to prosecution, Applicants would have to file, prosecute and maintain a total of fourteen applications at great time and expense to issue fourteen separate patents. Practically speaking, it is not likely that Applicants would be able to take that expensive route. The restriction requirement, as it now stands, will effectively and unfairly force the Applicants to forfeit patent coverage of many important aspects of their invention. The substantial cost benefit of keeping this application intact is combined with the belief that performing most of the searches at the same time will not involve an undue or unreasonable burden on the part of the Office. If anything, many of the searches overlap significantly, the scope of several searches will ultimately be the same and the Examiner will replicate her efforts many times over. Thus, Applicants urge the Examiner to withdraw the requirement to restrict this application or, at the very least, to modify the overwhelming number of groups.

Consistent with the foregoing remarks and in accordance with the requirement of 37 C.F.R. § 1.143, Applicants provisionally elect with traverse to prosecute the invention of Group I, Claims 1, 2, 6 and 8-13, insofar as they are drawn to an isolated avian hepatitis E virus, immunogenic composition or vaccine comprising the virus, and method of immunizing using the virus.

It is respectfully asked, nevertheless, that the Examiner seriously consider modifying the restriction requirement to combine the subject matter of Groups II-X, XII and XIV with the subject matter of Group I to comprise a single group drawn to Claims 1-6, 8-13, 19 and 20, in their entirety, due to the above remarks and for fair treatment of the invention, taken as a whole.

Applicants currently retain the nonelected subject matter to afford the Examiner the opportunity to reconsider the restriction requirement and, thus, for future consideration on the merits. It is to be understood that the provisional election is for procedural purposes only and that Applicants reserve the right to file a divisional application directed to the nonelected subject matter of this invention or a petition to modify the restriction requirement in the event that the restriction requirement is upheld.

Favorable treatment is respectfully solicited.

Respectfully submitted,  
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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service on February 18, 2003 with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

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